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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,017	04/17/2001	Elisabeth Lacy Belden	P-9312	6994
27581	7590	03/07/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			BUNIN, ANDREW M	
			ART UNIT	PAPER NUMBER
			3743	
DATE MAILED: 03/07/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/836,017	BELDEN ET AL.	
	Examiner	Art Unit	
	Andrew M. Bunin	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-49, 51 and 54-89 is/are pending in the application.
- 4a) Of the above claim(s) 46-49, 51 and 54-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 80-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 80-89 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg (US 6315789) in view of Hammerslag et al. (US 5308324). Cragg discloses a system fully capable of placing an electrical lead having an electrode assembly in a patient (column 7, lines 20-30), the system comprising: a guide wire 54 or stylet including a proximal portion and a distal portion; an electrode retention member (via 22, 34, etc.) fully capable of being adapted to temporarily couple the electrode assembly 10 to the guide wire 54 or stylet, the proximal portion 30 extending proximal to the electrode retention member (such as 22, 34) and the automatic distal portion 32 extending distal to the electrode retention member, and an elongate introducer (such as 18) including a lumen having a diameter sufficient to receive the proximal portion of the guide wire 54 or the stylet. Cragg doesn't explicitly disclose a guidewire including a deflection wire. However, Hammerslag et al. teach a steerable medical device that comprises a guidewire or stylet 60 that includes a deflection wire 70. Hammerslag et al. continue to disclose the deflection wire 70 as being disposed at the distal portion 64 of the guidewire 60 and coupled to a cap 90/65 (see Figures 7-11) (column 3, lines 28-32) (column 5, lines 6-9) (column 7, lines 26-30) (column 15, lines 22-41). Therefore, it

would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Cragg with the guidewire of Hammerslag et al. to create a well-balanced steering system and permit controlled lateral deflection of a distal tip (column 7, lines 7-16).

As for claims 81 and 82, Hammerslag et al. continue to teach a guidewire 10 that is steerable (Figure 6). In addition, Hammerslag et al. also teach the distal portion of the guidewire 10 as being shapeable (Figures 2 and 3).

Regarding claim 83, Cragg discloses an electrode retention member (22, 34) that has an outer surface adapted to form a press fit with an inner surface of a tubular portion of the electrode assembly to temporarily couple the electrode assembly 10 to the guide wire 54 as shown in Figure 8.

Regarding claim 84, Cragg discloses an electrode retention member that is formed of a polymeric plug (column 10, lines 40-60). Cragg discloses the use of polymers, and it can be broadly and reasonably interpreted to be a "plug."

Regarding claim 85, Cragg discloses an electrode retention member (22,34) that is fully capable of rotation when mounted upon the delivery system or guide wire 54.

Regarding claim 86, the electrode assembly would necessarily include an elongate lead extending proximally therefrom, and a diameter of the introducer lumen that is sufficient to slidably engage the lead (column 7, lines 20-58).

Regarding claim 87, Cragg does not explicitly recite a distal tip of the introducer that includes a nesting taper to aid in alignment of the electrode assembly for dislodging the electrode assembly. However, the tip of Cragg can be considered an equivalent

since the function of dislodging the electrode is equally performed. Therefore, it would have been obvious, if not inherent, to substitute one type of tip for another.

Regarding claim 88, Cragg discloses a distal tip of the introducer that is radiopaque (column 10, lines 40-60).

Response to Arguments

Applicant's arguments filed 12/21/05 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Cragg with the guidewire of Hammerslag et al. to create a well-balanced steering system and permit controlled lateral deflection of a distal tip (column 3, lines 7-16).

In response the deflection wire as not being disposed at a distal portion of the guidewire and coupled to a cap, Hammerslag et al. explicitly teach the deflection wire 70 as being disposed at a distal portion 64 of a guidewire 60 (Figure 7) (column 3, lines 28-32) (column 5, lines 6-9) (column 7, lines 26-30) (column 15, lines 22-41). In

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addition, Hammerslag et al. explicitly teach the deflection wire 88 as being coupled to a cap 90/65.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: US 6192280, US5639276, and US 6408213

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Bunin whose telephone number is (571)272-4801. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571)272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


AMB
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